PEDIATRICS/ORIGINAL RESEARCH

Do Children With Blunt Head Trauma and Normal Cranial

Computed Tomography Scan Results Require Hospitalization for Neurologic Observation?

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Study objective: Children evaluated in the emergency department (ED) with minor blunt head trauma, defined by initial Glasgow Coma Scale (GCS) scores of 14 or 15, are frequently hospitalized despite normal cranial computed tomography (CT) scan results. We seek to identify the frequency of neurologic complications in children with minor blunt head trauma and normal ED CT scan results.

Methods: We conducted a prospective, multicenter observational cohort study of children younger than 18 years with blunt head trauma (including isolated head or multisystem trauma) at 25 centers between 2004 and 2006. In this substudy, we analyzed individuals with initial GCS scores of 14 or 15 who had normal cranial CT scan results during ED evaluation. An abnormal imaging study result was defined by any intracranial hemorrhage, cerebral edema, pneumocephalus, or any skull fracture. Patients with normal CT scan results who were hospitalized were followed to determine neurologic outcomes; those discharged to home from the ED received telephone/mail follow-up to assess for subsequent neuroimaging, neurologic complications, or neurosurgical intervention.

Results: Children (13,543) with GCS scores of 14 or 15 and normal ED CT scan results were enrolled, including 12,584 (93%) with GCS scores of 15 and 959 (7%) with GCS scores of 14. Of 13,543 patients, 2,485 (18%) were hospitalized, including 2,107 of 12,584 (17%) with GCS scores of 15 and 378 of 959 (39%) with GCS scores of 14. Of the 11,058 patients discharged home from the ED, successful telephone/mail follow-up was completed for 8,756 (79%), and medical record, continuous quality improvement, and morgue review was performed for the remaining patients. One hundred ninetyseven (2%) children received subsequent CT or magnetic resonance imaging (MRI); 5 (0.05%) had abnormal CT/MRI scan results and none (0%; 95% confidence interval [CI] 0% to 0.03%) received a neurosurgical intervention. Of the 2,485 hospitalized patients, 137 (6%) received subsequent CT or MRI; 16 (0.6%) had abnormal CT/MRI scan results and none (0%; 95% CI 0% to 0.2%) received a neurosurgical intervention. The negative predictive value for neurosurgical intervention for a child with an initial GCS score of 14 or 15 and a normal CT scan result was 100% (95% CI 99.97% to 100%).

Conclusion: Children with blunt head trauma and initial ED GCS scores of 14 or 15 and normal cranial CT scan results are at very low risk for subsequent traumatic findings on neuroimaging and extremely low risk of needing neurosurgical intervention. Hospitalization of children with minor head trauma after normal CT scan results for neurologic observation is generally unnecessary. [Ann Emerg Med. 2011;58:315-322.] Please see page 316 for the Editor’s Capsule Summary of this article.

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**Editor’s Capsule Summary**

*What question this study addressed*

This prospective, multicenter, observational cohort study of 13,543 children with minor head trauma (Glasgow Coma Scale score 14) and normal emergency department (ED) CT scan results determined the proportion of patients with subsequent abnormal CT or magnetic resonance imaging scan results or neurosurgical intervention.

*What this study adds to our knowledge*

Children with minor head trauma and a normal ED CT scan result are at extremely low risk for a subsequent abnormal scan result or a neurosurgical intervention.

*What this study adds to our knowledge*

Children with minor head trauma and a normal ED CT scan result are at extremely low risk for a subsequent abnormal scan result or a neurosurgical intervention.

*How this is relevant to clinical practice*

Children who incurred minor head trauma and had a negative CT scan result can be safely observed at home. The study provides no information about whether the CT was a necessary part of the evaluation.

## INTRODUCTION

Traumatic brain injury is the leading cause of death and disability in children older than 1 year.1 Cranial computed tomography (CT) is the diagnostic test of choice to urgently identify intracranial hemorrhage in children with blunt head trauma. Although CT scanning is the criterion standard and has been used with increasing frequency,2 most children presenting to emergency departments (EDs) after minor head trauma do not require CT scanning. When CT scanning is performed in children with minor head trauma (Glasgow Coma Scale [GCS] scores of 14 or 15), more than 90% are shown to have normal cranial CT scan results.3-5 On occasion, children with negative initial CT scan results may undergo further diagnostic imaging with repeated CT scans, magnetic resonance imaging (MRI), or positron emission tomography scanning. These additional diagnostic tests occasionally identify injuries that were too small to characterize, were unapparent on the initial CT scan, or that evolved over time.6-8

Many children with minor head trauma are hospitalized for neurologic observation despite normal ED cranial CT scan results. 9-11 This practice allows for repeated and frequent neurologic examinations to rapidly detect clinical deterioration.

In addition, patient hospitalization creates opportunities for patient/family counseling and neurocognitive evaluation for identification of concussive symptoms. Neurologic deterioration after a negative CT scan result, however, is rare in adults with minor head trauma evaluated in EDs.12-14 Limited pediatric data also suggest that hospitalization is likely unnecessary for children with minor head trauma and normal CT scan results, although the confidence intervals (CIs) around the point

estimates of risk are wide.9,10,15

The objective of this study was to identify the frequency with which children with minor blunt head injury and normal initial CT scan results have either traumatic findings identified on a subsequent neuroimaging study or experience neurologic deterioration resulting in the need for neurosurgery (by determination of the negative predictive value of an initial normal CT scan result for neurosurgical intervention). Precise estimates of these risks would allow clinicians to make evidencebased decisions about the need for hospitalization of these patients. We hypothesize that children with minor head trauma and normal initial ED CT scan results rarely develop acute neurologic complications or clinical deterioration, such that hospitalization of these patients is typically unnecessary.

# MATERIALS AND METHODS

**Study Design and Setting**

This was a planned secondary analysis of a large prospective observational cohort study at 25 EDs across the United States from June 2004 to September 2006. The study was approved by each participating site’s institutional review board. The methods of the primary study are described elsewhere.3 Methodology specific to this study is described below.

**Selection of Participants**

We analyzed children younger than 18 years who were evaluated in an ED for nontrivial blunt head trauma and who underwent cranial CT scanning during this evaluation. This included patients with isolated head trauma, as well as those with head and multisystem trauma. All CT scans were obtained at the discretion of the treating physicians. Patients were excluded from this analysis for ED GCS scores less than 14, if they had traumatic findings (defined as extra-axial hematomas, subarachnoid or intraventricular hemorrhage, cerebral hemorrhage/contusion or edema, diffuse axonal hemorrhage, pneumocephalus, or skull fracture) identified on their initial ED cranial CT scans, or if there was a history of coagulopathy or ventricular shunt.

**Data Collection and Processing**

Historical and physical examination findings were documented on a standardized case report form before knowledge of the CT scan results. The history and physical examination findings that were documented by the treating clinicians and are pertinent to this analysis included the initial GCS score, the presence of vomiting, and the presence of either isolated head trauma or head trauma in association with significant nonhead trauma (ie, multisystem trauma). These variables were collected because vomiting is an important symptom for which patients may undergo hospitalization for intravenous fluid administration and patients with multisystem trauma may require hospitalization for nonhead injuries.

Cranial CT and MRI results were obtained from the final dictated attending radiologist report at each study site. For this study, CTs or MRIs were considered to have traumatic findings if any of the following were present: intracranial hemorrhage (epidural hematoma, subdural hematoma, cerebral contusion, intraventricular hemorrhage, and subarachnoid hemorrhage), cerebral edema, diffuse axonal hemorrhage, pneumocephalus, or any skull fracture.

Patients discharged home from the ED received telephone follow-up at least 1 week after the ED visit to determine whether repeated CT scanning or MRI was performed and to determine the occurrence of neurologic complications, including neurosurgical intervention. For individuals not available by telephone follow-up, we mailed the telephone survey to their listed address. If the survey was not returned by mail, we then reviewed the patients’ medical records, ED process improvement records, trauma registry records, and county morgue documents to identify any patients with a subsequent CT or MRI with traumatic findings, neurosurgery, or death from a traumatic brain injury.

**Outcome Measures**

The main outcome measures of interest were traumatic findings on subsequent CT or MRI and neurosurgical intervention (eg, craniotomy, ventricular drainage). For those patients determined to have a traumatic finding on a subsequent CT or MRI, we performed a detailed review of the medical records to identify the number of days hospitalized and specific therapy for the traumatic finding, including any neurosurgical procedure or tracheal intubation. For data analysis, we assumed those patients without repeated neuroimaging (CT or MRI) and no evidence of neurologic deterioration on follow-up were without traumatic brain injury.

**Primary Data Analysis**

Data are described with simple descriptive statistics. We determined the negative predictive value for a negative (normal) ED CT scan result for identifying those patients not needing a neurosurgical intervention. Ninety-five percent CIs are provided where appropriate. We performed the data analysis with SAS statistical software (version 9.2; SAS Institute, Inc., Cary, NC).

**Sensitivity Analyses**

We performed a sensitivity analysis to address the issue of potentially failing to identify subsequent traumatic findings on CT in those patients discharged from an ED but who then

failed telephone/mail follow-up. In this sensitivity analysis, we applied the rate of traumatic findings on cranial imaging subsequently identified in patients admitted to the hospital to those who were discharged from the ED and were without telephone/mail follow-up. This represents a “worse-case scenario” because the admitted population is at higher risk for the outcome than those discharged from the ED.

## RESULTS

The primary study enrolled 43,904 (77%) of 57,030 eligible patients. In the primary study population, there were no differences between patients enrolled and those missed with regard to CT rates or traumatic brain injury on CT.3 The Figure demonstrates the flow diagram of patients from the primary study population to those analyzed for the current study. A total of 13,543 patients met inclusion/exclusion criteria for the current analysis, including 12,584 (93%) with initial GCS scores of 15 and 959 (7%) with initial GCS scores of 14.

The median age for all patients in this analysis was 8.9 years (interquartile range 2.8 to 14.3 years); 2,724 (20%) patients were younger than 2 years, and 8,563 (63%) were boys. Telephone or mail follow-up was successful for 79% of patients who were discharged home from the ED.

Of the 12,584 patients with initial GCS scores of 15 and normal ED CT scan results, 10,477 (83%) were discharged home from an ED and 2,107 (17%) were hospitalized; 8,298 of the 10,477 (79%) discharged patients received successful telephone/mail follow-up. Of the 10,477 patients discharged, 184 (2%) received repeated neuroimaging, including 96 (0.9%) with subsequent CT scans, 79 (0.8%) with MRI scans, and 9 (0.1%) with both CT and MRI scans. Four (0.04%) patients had traumatic findings visualized on neuroimaging (1 on CT scan and 3 on MRI). None (0%; 95% CI 0% to 0.04%) had a neurosurgical intervention.

Of the 2,107 hospitalized patients with GCS scores of 15 and normal cranial CT scan results, 116 (6%) had repeated neuroimaging. These included 83 (4%) patients with CT scans, 26 (1%) with MRI scans, and 7 (0.3%) with both CT and MRI. Eleven (0.5%) patients had traumatic findings on neuroimaging (7 on CT and 4 on MRI). None (0%; 95% CI 0% to 0.2%) had a

neurosurgical intervention. Of these 2,107 patients, 1,133 (54%) were considered by the treating physician at the ED evaluation to have isolated head trauma, and 372 (18%) were documented as having vomiting at or before initial ED evaluation.

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| --- |
| Figure. Study patient flow. |

The 15 patients (both those patients discharged from the ED and those hospitalized) with initial GCS scores of 15 who had traumatic findings on follow-up CT or MRI scans are described in the Table. The negative predictive value for neurosurgical intervention of a normal ED CT scan result in a patient with an initial ED GCS score of 15 was 100% (95% CI 99.97% to 100%). One patient with an initial GCS score of 15 and a normal ED CT scan result was found to have a subacute subdural hematoma on an MRI performed within 24 hours of the ED visit for a motor vehicle crash. Because of the MRI characteristics of the injury, the treating physicians considered the subdural hematoma to have occurred before the motor vehicle crash, and the child was further evaluated for nonaccidental trauma. For study purposes, this patient was not considered to have a traumatic brain injury related to the motor vehicle crash and did not require neurosurgical intervention.

Five hundred eighty-one (61%) of the 959 patients with normal CT scan results and initial GCS scores of 14 were discharged from an ED and 378 (39%) were hospitalized. Four hundred fifty-eight of the 581 (79%) discharged patients received successful telephone/mail follow-up. Of the 581 patients discharged, 13 (2%) received repeated neuroimaging. These included 5 (0.9%) patients with CT scans, 7 (1%) with MRI scans, and 1 (0.2%) with both CT and MRI. One (0.2%) patient had a traumatic finding identified on CT, and none had traumatic findings identified on MRI. None (0%; 95% CI 0% to 0.6%) underwent neurosurgical intervention.

Of the 378 patients hospitalized with initial GCS scores of

14, 21 (6%) received repeated neuroimaging. These included 12

(3%) patients with CT scans, 4 (1%) with MRI scans, and 5 (1%) with both CT and MRI. Five (1%) patients had traumatic findings visualized on repeated neuroimaging (3 on CT and 2 on MRI). None (0%; 95% CI 0% to 1.0%) had a neurosurgical intervention. Of the 378 hospitalized patients, 240 (64%) were considered by the treating physician during ED evaluation to have isolated head trauma, and 64 (18%) were documented as having vomiting at or before initial ED evaluation.

The 6 patients with traumatic findings on repeated CT or MRI scan are described in the Table. The negative predictive value for neurosurgical intervention of a normal ED CT scan result in patients with initial GCS scores of 14 was 100% (95% CI 99.6% to 100%).

**Sensitivity Analyses**

For patients with GCS scores of 15 who were admitted to the hospital, the proportion of subsequent traumatic findings was 0.5% (11/2,107). Application of this proportion to the 2,179 discharged patients with GCS scores of 15 who did not have successful telephone/mail follow-up would suggest that another 11 patients may have had traumatic findings on subsequent cranial imaging. For patients with GCS scores of 14 who were admitted to the hospital, the proportion of subsequent traumatic findings was 1% (5/378). Application of this proportion to the 123 patients with GCS scores of 14 who did not receive successful telephone/mail follow-up would suggest that 1 patient may have had traumatic findings on

Table. Characteristics of patients with traumatic findings on repeated CT/MRI after a normal ED CT scan result.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Age, Years | Mechanism of Injury | Image | | CT/MRI Findings | Days  Hospitalized |
| Patients with GCS score of 15  5  5  5.5 6  7.5  8  8  10  12.5  14.5  14.5 15  15.5  16  17  Patients with GCS score of 14  0.25  1.5  6  11  14.5  17  *SAH*, Subarachnoid hemorrhage; *SDH*, subdural  \*Patients considered to have isolated head † Patients with other significant injuries besides None of the 21 patients met the low-risk present in all patients).3 | Fall from 3–5 ft  Fall (ground level)  Bike crash/fall  Ran into stationary object  Auto vs pedestrian  ATV vs tree  High-speed MVC  Auto vs bicyclist  Assault  Hockey  ATV  Football  High-speed MVC  Car surfing at 20 miles/h  Bike crash/fall  Fall from 3 ft  Fall from 3 ft  Ejected from vehicle  Auto vs pedestrian  Bike crash/fall  Soccer  hematoma; *ATV*, all-terrain vehicle;  trauma by the treating physician. the head injury.  criteria for clinically important traumatic | MRI  MRI CT  MRI  CT  CT  CT  MRI CT  MRI CT  MRI  CT  CT  MRI  CT  CT  MRI CT  MRI  CT  *MVC*, motor  brain injury from | | SAH  Cerebral microhemorrhages  Skull fracture  Cerebral contusion  SDH  Cerebral contusion  Cerebral contusion  Cerebral hematoma and DAI  Extra-axial hematoma  DAI  SDH  Cerebral contusion and edema  SDH and SAH  Cerebral edema, SAH, cerebral hematoma  Cerebral contusion and edema  Skull fracture  Skull fracture  Cerebral contusion  Cerebral edema, cerebral hematoma  Cerebral contusion  SDH  vehicle crash; *DAI*, diffuse axonal injury.  the previously derived rule (ie, at least 1 variable | 4\*  1\*  1\*  1\*  †  3  †  3  †  3  †  18  Not hospitalized\*  Not hospitalized\*  †  2  Not hospitalized\*  1\*  2\*  Not hospitalized\*  Not hospitalized\*  1\*  †  5  2\*  4\*  1\*  in the rule was |
| subsequent cranial imaging. If this were true, the proportion of patients with subsequent traumatic findings on cranial imaging would increase from the identified proportion of 21 of 13,543 (0.16%) to 33 of 13,543 (0.24%). Thus, it is unlikely that those patients lost to telephone/mail follow-up would substantially affect the results or conclusions of this study. All patients lost to telephone/mail follow-up had other forms of follow-up (see “Data Collection and Processing” section above).  For the conclusions of this study to change, the proportion of patients with traumatic findings subsequently identified after a normal cranial CT scan result would likely need to exceed 1% in the entire population. For this to occur, 5% of the patients who were lost to telephone follow-up would need to have traumatic findings on a subsequent CT or MRI (ie, 115 of the 2,302 patients lost to telephone follow-up). Such a proportion would be highly unlikely, given that this far exceeds the proportion with subsequent traumatic findings on cranial imaging in those admitted to the hospital and that the additional methods of follow-up did not identify any patients with traumatic findings among those lost to telephone follow-up.  **LIMITATIONS**  The study has some limitations. Not all patients enrolled into the primary study underwent CT. This subanalysis is from a subset of the main study population, but because they were selected for | | | CT during ED evaluation, the population consists of patients considered at high risk for traumatic findings on CT by the treating physicians. Most patients with negative initial CT scan results did not undergo a repeated CT or MRI scan. It is possible that patients who did not undergo repeat imaging would have had traumatic findings had they received imaging a second time. The importance and necessity of identifying traumatic brain injuries that do not require acute intervention is unclear.  We successfully performed telephone/mail follow-up for the majority of patients. It is possible that some patients who were lost to telephone/mail follow-up had traumatic findings identified on CT or MRI at another hospital and were not identified through our medical record, continuous quality improvement, or morgue review. We performed a sensitivity analysis to determine the effect of potential missed traumatic findings on these patients lost to telephone/mail follow-up. The results of that analysis suggest minimal if any effect on the conclusions of this study. Furthermore, a recent large population-based study suggested that the incidence of delayed diagnosis of traumatic brain injury is less than 0.6 cases per 100,000 children per year (although most of the cases identified were not initially evaluated in an ED).16  The exact reasons for hospitalization after normal cranial CT scan results were not specifically collected. Therefore, although most hospitalized patients with physician-documented isolated | | |

head trauma and normal cranial CT scan results were likely admitted for reasons related to the head trauma, we cannot be sure that other indications (social admissions) on occasion did not play a role in the admission decision.

We assessed the final faculty radiologists’ interpretations of the CT scans. Although the trend in radiology is “real-time” CT interpretations by board-certified radiologists, emergency physicians at some centers make clinical decisions on initial CT interpretations, which in many centers could be from the radiology house staff. The results of this study may not be as generalizable to radiology house staff interpretations. However, in the community setting in which most children with minor head trauma present, radiology house staff are not present to interpret CT scans. Finally, we did not assess long-term neurocognitive function in these patients. Brain injury may still occur despite a normal ED cranial CT scan result. Currently, no evidence suggests that these patients benefit from acute hospitalization, although further outpatient evaluation and follow-up for postconcussive symptoms is likely warranted.17,18

# DISCUSSION

This large, prospective study demonstrates that children with minor head trauma in EDs (defined by initial ED GCS scores of 14 or 15) and normal cranial CT scan results infrequently undergo repeat cranial CT scanning or MRI. Furthermore, in this large study, few children with normal initial cranial CT scan results after minor head trauma had traumatic findings identified on subsequent neuroimaging studies. Most important, this study demonstrates that those children with minor head trauma and normal ED cranial CT scan results are at such low risk for neurologic deterioration and neurosurgical procedures that hospitalization for serial neurologic examinations is typically not necessary.

Compelling data from studies of adult patients with blunt head trauma also suggest that hospitalization of patients with blunt head trauma after normal cranial CT scan results is unnecessary. The greatest amount of evidence in this regard is a multicenter study of 1,788 alert adults with head trauma, in which only 1 patient underwent a craniotomy after a normal CT scan result. This patient had a skull fracture that was missed on initial CT interpretation but was subsequently identified and surgically repaired.12 The mechanisms, clinical presentations, spectrum of injuries, and responses to injury in children who experience head trauma, however, differ from that of adults.19 Thus, extrapolating results from adult head trauma studies to the pediatric population for clinical decisionmaking may not be appropriate.

Previous research evaluating the need for hospitalization of children with head trauma is limited by small numbers studied in single centers or retrospective study designs that do not allow for reliable, precise, and definitive assessment of rates of complications at follow-up.9,10,15 A study of 73 children with minor head trauma and normal initial CT scan results demonstrated that none developed complications; however, 90% of the patients were followed for less than 48 hours, such that any event occurring beyond that period was not identified.15 A second pediatric study retrospectively identified 400 children with blunt head trauma and normal cranial CT scan results in the ED of a Level I trauma center and assessed future neurologic deterioration by a statewide hospital admission reporting system and reported deaths.10 Four patients were identified as being subsequently hospitalized, including 2 with traumatic brain injury on follow-up CT scans, one of whom (a child receiving warfarin who developed a delayed subdural hematoma) underwent neurosurgery. In the current study, we excluded children with congenital and acquired coagulation disorders because it is difficult to generalize the outcomes of that particular population to the general population of head-injured children.

A retrospective analysis of 1,033 children with isolated head trauma in the National Pediatric Trauma Registry found that average hospital length of stay for children with isolated head trauma and normal CT scan results was 1.2 days and that none underwent neurosurgery.9 In contrast to previous studies, the current study provides a very large sample size of children from multiple centers, with good generalizability and prospective follow-up to determine precise risk estimates for neurologic deterioration in children with minor head trauma after normal, initial ED cranial CT scan results.

Despite the results of the current study, there remain indications for hospitalizing some children with minor head trauma and normal initial CT scan results. A subgroup of these patients will have injuries other than of the head (ie, multisystem trauma) that require hospitalization. An additional subgroup of patients with isolated head injury, however, will remain symptomatic and require neurologic observation and intravenous fluid administration because of an inability to tolerate fluids. Of the hospitalized children in this study with minor head trauma and negative CT scan results, 436 (18%) had vomiting documented.

Hospitalized patients were more likely to undergo subsequent imaging studies (CT or MRI), and they were more likely to have traumatic findings identified on these subsequent imaging studies. Part of the reason that follow-up neuroimaging studies were more common in hospitalized patients is likely ease and accessibility. However, emergency physicians were also likely admitting patients with more severe head injuries who were more symptomatic despite normal initial CT scan results. Regardless, none of the traumatic findings identified required neurosurgical intervention.

Some investigators have also argued that many children with isolated skull fractures on CT do not require hospitalization,20 and even patients with certain minor traumatic brain injuries and GCS scores of 15 may also not require hospitalization.3,21 However, in this study we did not formally assess the actual need for hospitalization among those patients with a traumatic finding on initial ED CT scan, although several patients with traumatic findings found on subsequent imaging studies were never hospitalized.

Of the 2,485 hospitalized patients, more than half were documented by the treating physician as having isolated head trauma. Although some likely had other reasons for hospitalization (eg, social indications, concerns for other injuries not identified), many were likely hospitalized simply for neurologic observation. This suggests that hospitalization for neurologic observation even after negative CT scan results continues at many medical centers across the United States, even specialty pediatric centers such as those participating in this study. Although some patients with minor blunt head trauma and normal cranial CT scan results may require hospitalization for specific reasons, many patients in our study population did not. Decreasing hospitalization rates among this population has the potential to reduce medical costs, reduce hospital crowding, and provide patients and their families more optimal care. These findings cannot be applied to those children excluded from the study, including those receiving anticoagulant medications, those with ventricular shunts, or those with initial GCS scores less than 14.

In conclusion, children with initial ED GCS scores of 14 or 15 and normal cranial CT scan results after blunt head trauma are at very low risk for subsequent traumatic findings on CT or MRI scan and at extremely low risk of needing neurosurgical intervention. Routine hospitalization for neurologic observation of children with minor blunt head trauma and normal cranial CT scan results is generally unnecessary.

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## APPENDIX.

The following individuals were participating in PECARN when this study was initiated:

PECARN Steering Committee: N. Kuppermann, Chair; E. Alpern, J. Chamberlain, J. M. Dean, M. Gerardi, J. Goepp, M. Gorelick, J. Hoyle, D. Jaffe, C. Johns, N. Levick, P. Mahajan, R. Maio, K. Melville, S. Miller (deceased), D. Monroe, R. Ruddy, R. Stanley, D. Treloar, M. Tunik, A. Walker. MCHB/EMSC liaisons: D. Kavanaugh, H. Park.

Central Data Management and Coordinating Center: M. Dean, R. Holubkov, S. Knight, A. Donaldson.

Data Analysis and Management Subcommittee: J. Chamberlain, Chair; M. Brown, H. Corneli, J. Goepp, R. Holubkov, P. Mahajan, K. Melville, E. Stremski, M. Tunik.

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Protocol Concept Review and Development Subcommittee: D. Jaffe, Chair; K. Brown, A. Cooper, J. M. Dean, C. Johns, R. Maio, N. C. Mann, D. Monroe, K. Shaw, D. Teitelbaum, D.

Treloar.

Quality Assurance Subcommittee: R. Stanley, Chair; D. Alexander, J. Brown, M. Gerardi, M. Gregor, R. Holubkov, K. Lillis, B. Nordberg, R. Ruddy, M. Shults, A. Walker.

Safety and Regulatory Affairs Subcommittee: N. Levick, Chair; J. Brennan, J. Brown, J. M. Dean, J. Hoyle, R. Maio, R. Ruddy,

W. Schalick, T. Singh, J. Wright.

Participating centers and site investigators are listed below in alphabetical order: Atlantic Health System/Morristown Memorial Hospital (M. Gerardi), Bellevue Hospital Center (M. Tunik, J. Tsung), Calvert Memorial Hospital (K. Melville), Children’s Hospital Boston (L. Lee), Children’s Hospital of Michigan (P. Mahajan), Children’s Hospital of New York–Presbyterian (P. Dayan), Children’s Hospital of Philadelphia (F. Nadel), Children’s Memorial Hospital (E. Powell), Children’s National Medical Center (S. Atabaki, K. Brown), Cincinnati Children’s Hospital Medical Center (T. Glass), DeVos Children’s Hospital (J. Hoyle), Harlem Hospital Center (A. Cooper), Holy Cross Hospital (E. Jacobs), Howard County Medical Center (D. Monroe), Hurley Medical Center (D. Borgialli), Medical College of Wisconsin/Children’s Hospital of Wisconsin (M. Gorelick, S. Bandyopadhyay), St. Barnabas Health Care System (M. Bachman, N. Schamban), SUNY–Upstate Medical Center (J. Callahan), University of California, Davis Medical Center (N. Kuppermann, J. Holmes), University of Maryland (R. Lichenstein), University of Michigan (R. Stanley), University of Rochester (M. Badawy, L. Babcock-Cimpello), University of Utah/Primary Children’s Medical Center (J. Schunk), Washington University/St. Louis Children’s Hospital (K. Quayle, D. Jaffe), Women and Children’s Hospital of Buffalo (K. Lillis).